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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,121	01/13/2000	Ralf Reiner Schumann	0107-020P/GPK	9305

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GABRIEL P. KATONA
GOODWIN PROCTER L.L.P.
599 LEXINGTON AVENUE
40TH FLOOR
NEW YORK, NY 10022

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 11/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/484,121

Applicant(s)

SCHUMANN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-18, 22, 23 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 12-18, 22 and 23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Groups III and IV, claims 23-27 with traverse in Paper No. 24, filed September 16, 2002 has been received. Claim 23 belongs to Group II, drawn to a method of making LBP protein by expression, while claims 24-27, which replace the original claims 19-21, are directed to a method of treating septicemia. In the Supplemental Response to the Restriction Requirement filed September 19, 2002 (Paper No. 25), applicant canceled claims 24-27, added new claims 28-33, and elected claims 28-33 with traverse. The traversal is on the ground(s) that claims 28-33 which replace claims 19-21, are not directed to different inventions. Upon reviewing claims 28-33, the argument is persuasive, thus claims 28-33 are examined.

Claim Objections

2. Claim 28 is objected to because of the use of the term "protein binding lipopolysaccharide (LBP)". Use of the term "lipopolysaccharide binding protein (LBP)" is suggested.
3. Claim 31 is objected to because of the use of the term "at least one of rabbit of rat LBP". Use of "at least one of rabbit or rat LBP" is suggested.
4. Claim 32 is objected to because of the use of a misspelled word "ehrtrion".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 28-33 are indefinite because the claims lack essential steps in the method for treating septicemia. The omitted steps are: effective amount of the agent administered and the outcome of the treatment. Claims 29-33 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.
7. Claims 28-33 are indefinite because of the use of the term “and/or”. The term “and/or” renders the claim indefinite, it is unclear whether the limitation after “and/or” is included or not, and if included is to be read as an alternative “or” or the conjunctive “and”. Use either “or” or “and” not both. Claims 29-33 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.
8. Claims 28-33 are indefinite because of the use of the term “its variants, mutants or hybrid proteins”. The term “its variants, mutants or hybrid proteins” renders the claim indefinite, it is not clear what variants, mutants or hybrid proteins are intended, e.g., what modification is made on the LBP, or what is the other partner for the hybrid protein of LBP. It is also not clear whether the variants, mutants or hybrid proteins have the same function as LBP. Claims 29-33 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.
9. Claims 32 and 33 are indefinite because of the use of the term “LPS”. The term “LPS” renders the claim indefinite, it is unclear what the term means. A full spelled out word should be indicated. Claim 32 is also indefinite because of the use of the term “of LBP with the LPS

binding site of the limulus anti-LPS factor (LALF)". The cited term renders the claim indefinite, it is unclear what the term means

10. Claim 33 is indefinite because of the use of the term "at the LPS binding site (amino acids 91-101) by individual exchanges of amino acids". The term "at the LPS binding site (amino acids 91-101) by individual exchanges of amino acids" renders the claim indefinite, it is unclear what exchanges are made at amino acids 91-101, e.g., is it a conservative substitution, or where and how many substitutions are made at the LPS binding site. It is also not clear which peptide sequence is referred to regarding the amino acids 91-101 because the claim does not recite the reference "SEQ ID NO:" .

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 28, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott *et al.* (WO 94/25476).

Scott *et al.* teach a pharmaceutical composition comprising a therapeutically effective amount of a BPI variant, a LBP variant, or an LBP-BPI chimera and a pharmaceutically acceptable carrier, and a method of treating endotoxin-related disorders such as sepsis and septic shock using the composition (page 2, line 34-page 3, line 4; pages 13, 14, 18, 22, 23, 25; Tables 3-6; claim 28). The composition containing a LBP variant such as L_{(S77->K)(R86->K)(S96->K)(L118->K)(R126->K)} (NCY141 in Table 3) which has a mutation at position 96 (claim 33), or a LBP-BPI

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chimera such as L_{197(143->V)}B_{200-456(N206->D)} (NCY 103 in Table 3) which is a hybrid protein of LBP (L) and BPI (B) (claim 32).

12. Claims 28 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Heavner *et al.* (WO 95/08560).

Heavner *et al.* teach a pharmaceutical composition comprising a peptide derived from a portion of amino acids 95-104 of LBP such as Arg-Lys-Ser-Phe-Phe-Lys-Leu-Gln-Gly-Ser-Phe-Asp-Val-Ser-Val-NH₂ (SEQ ID NO:1) and its variants (SEQ ID NO:2-64, see pages 9-12, 21-22 and Examples 1-9), and a method for treating sepsis caused by gram-negative bacteria using the composition (page 5, line 12; claims 28 and 33).

Claim Rejections - 35 USC § 102&103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 29-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Scott *et al.* (WO 94/25476).

Scott *et al.* teach a pharmaceutical composition comprising a therapeutically effective amount of a BPI variant, a LBP variant, or an LBP-BPI chimera and a pharmaceutically

acceptable carrier, and a method of treating endotoxin-related disorders such as sepsis and septic shock using the composition (page 2, line 34-page 3, line 4; pages 13, 14, 18, 22, 23, 25; Tables 3-6), where LBP can be human, mouse or rabbit LBP in the LBP-BPI chimera (page 11, lines 1-5; page 18, lines 5-13; Fig. 5; claims 29-31). Claims 29-31 are anticipated as the construct recited in the claimed process would have been anticipated by teaching of producing chimeras of LBP and BPI (See page 11, lines 1-5; page 18, lines 5-13). In the alternative that it would have been obvious if not anticipated that the teaching regarding chimeric constructs would have motivated one of ordinary skill in the art to have made substitutions of rabbit, human or mouse (murine) LBP (See Fig. 5 which discloses various LBPs). The practice of the process with these constructs would have resulted in the claimed invention which was at least obvious if not anticipated from the cited reference.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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Chih-Min Kam, Ph. D.
Patent Examiner

CMK

November 20, 2002


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600